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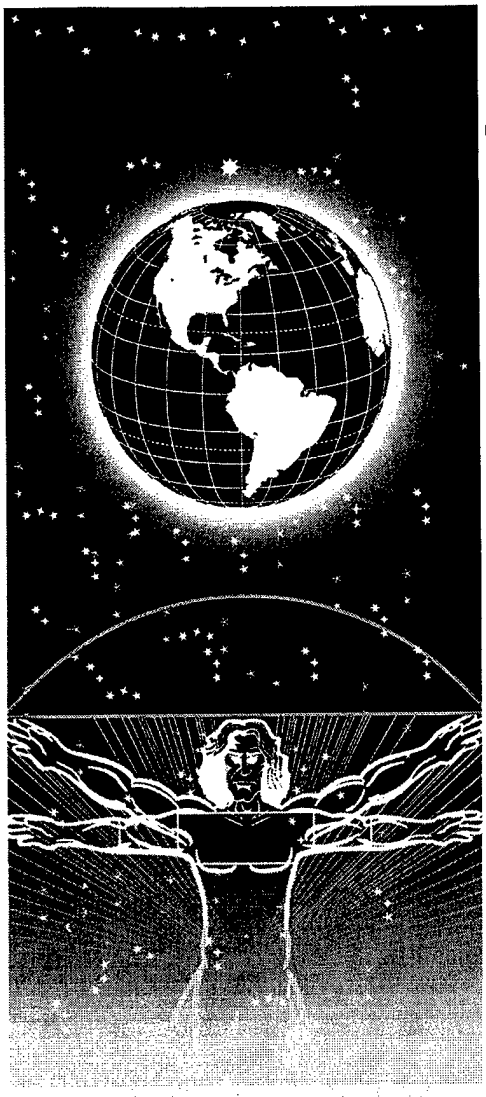

UNITED STATES AIR FORCE RESEARCH LABORATORY

TESTING AND EVALUATION OF THE INTERNATIONAL BIOMEDICAL, INC., MODEL 185M, AIRBORNE LIFE SUPPORT SYSTEM.

Butch O. Blake

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June 2000

NOTICES

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The International Biomedical, Inc., Model 185M, Airborne Life Support System (ALSS) is an infant transport incubator. It provides an environment to sustain an infant's life support requirements while being transported. The ALSS's standard infant chamber circulates heated air and comes equipped with one main door, one head door, and two hand ports. The ALSS's main door allows access for infant placement inside the infant chamber as well as further access for medical care. To prevent excessive heat loss, the main door has hand ports to allow infant care without opening the main door. The ALSS provides medical grade oxygen using "E" size tanks secured underneath the unit. The unit operates off of 115 VAC/60 and 400 Hz and internal rechargeable battery. The unit weighs approximately 86.9 lbs. Its dimensions are 40.0 in. W. X 19 5/8 in. H. X 22 ½ in. D.

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Major James Sylvester	Program Manager
1Lt Jonathan Raker	Biomedical Engineer
TSgt Allen Gray	NCOIC, Life Support Section
Mr. Victor Elizondo	Electronics Technician

TESTING AND EVALUATION OF THE INTERNATIONAL BIOMEDICAL, INC., MODEL 185M, AIRBORNE LIFE SUPPORT SYSTEM

BACKGROUND

Air Mobility Command requested the Air Force Medical Equipment Development Laboratory (AFMEDL) participate in evaluating and approving International Biomedical, Inc., Model 185M Airborne Life Support System (ALSS) for use on board USAF aeromedical evacuation aircraft. Specific components of the International Biomedical, Inc., Model 185M Airborne Life Support System that underwent evaluation included: the International Biomedical, Inc., Model 185M system: (S/N: 538); and the International Biomedical, Inc., Hook Attachment Kit (P/N: 7319560) as well as the stretcher rail X2 (P/N: 3641081) for securing the ALSS to NATO litters. All components of the model 185M were tested for airworthiness. Throughout this report, the term Equipment Under Test (EUT) refers to the model 185M and all internal and external components.

DESCRIPTION

The EUT is an infant transport incubator. It provides an environment to sustain an infant's life support requirements while being transported. The EUT's standard infant chamber circulates heated air and comes equipped with one main door, one head door, and two hand ports. The EUT's main door allows access for infant placement inside the infant chamber as well as further access for medical care. To prevent excessive heat loss, the main door has hand ports to allow infant care without opening the main door. The EUT provides medical grade oxygen using "E" size tanks secured underneath the unit. The unit operates off of 115 VAC/60 and 400 Hz electricity and a 12 V DC internal rechargeable battery. The unit weighs approximately 86.9 lbs. Its dimensions are 40.0 in. W. X 19 5/8 in. H. X 22 ½ in. D.

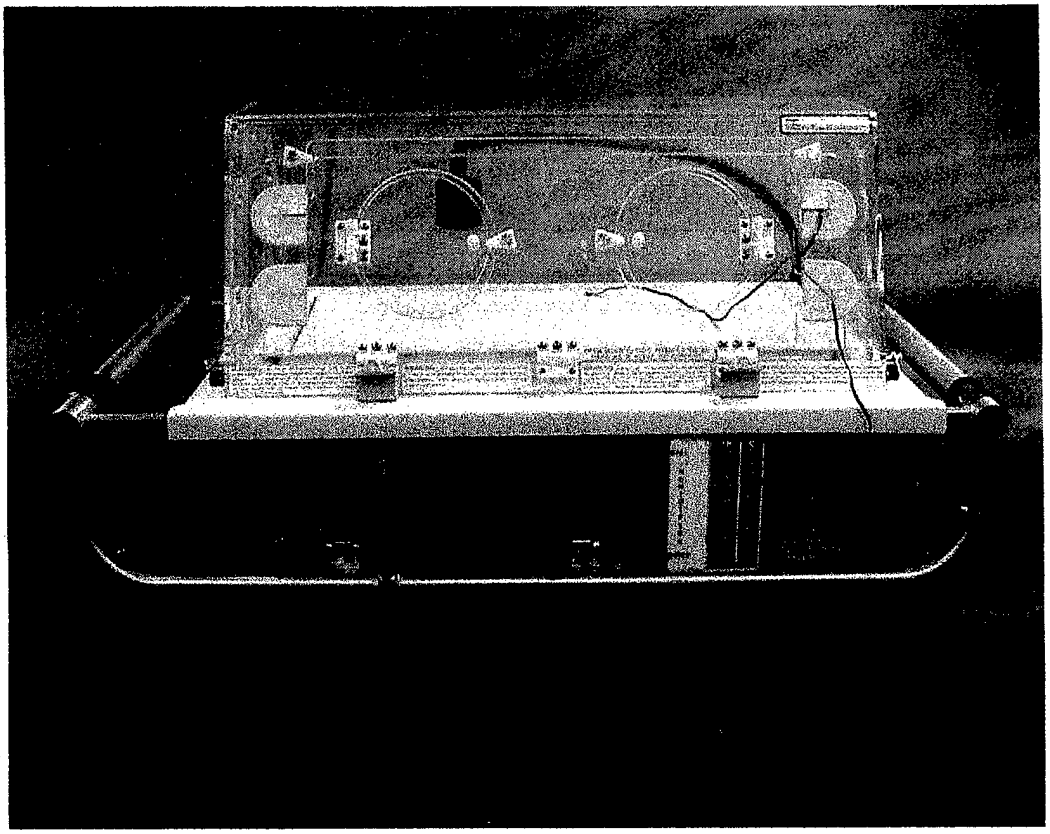

Figure 1. International Biomedical, Inc., Model 185M Airborne Life Support System

PROCEDURES

Test methods and performance criteria were derived from nationally recognized performance guidelines (1 & 2), military standards (3-8), and manufacturer's literature (9). The AFMEDL Procedures Guide describes additional safety and human interface issues to be considered during equipment testing (10). A test setup and performance check was developed specific to this EUT to verify its proper functioning under various testing conditions. All tests were conducted by AFMEDL personnel assigned to the Protective Systems Branch, Biodynamics and Protection Division, Human Effectiveness Directorate, Air Force Research Laboratory, Brooks AFB, Texas, unless otherwise noted.

The EUT was subjected to various laboratory and in-flight tests to observe and evaluate its performance under anticipated operational conditions.

1. Initial Inspection

2. Vibration

3. Electromagnetic Interference (EMI)

4. Thermal/ Humidity Environmental Conditions, encompassing:

    a. Hot Operation

    b. Cold Operation

    c. Humidity Operation

    d. Hot Temperature Storage

    e. Cold Temperature Storage

5. Hypobaric Conditions

    a. Cabin Pressure/Altitude

    b. Rapid Decompression to simulated flight level

6. Airborne Performance

INITIAL INSPECTION AND TEST PREPARATION

a. The EUT was inspected for quality of workmanship, production techniques, and pre-existing damage.

b. The EUT was checked to ensure it met safety requirements and operating characteristics established in National Fire Protection Agency (NFPA) 99 (1); AFI 41-203, Electrical Shock Hazards (3); and AFI 41-201, Equipment Management in Hospitals (4). Ground resistance and leakage current measurements were made at 115 VAC/60 Hz and 115 VAC/400 Hz.

c. The EUT was examined to ensure it met basic requirements for human factor design as outlined in MIL-STD 1472 (5).

d. A test setup and performance check was developed to evaluate the EUT's operation in accordance with manufacturer/customer specifications throughout the various testing conditions.

TEST SETUP

Test Setup:

1. Place the ALSS device in the simulated environment for which it will be tested.

2. Set up Fluke multimeter with temperature probe attachment to record temperature inside the incubator. Place temperature probe inside incubator.

3. Plug the AC power supply cord into a grounded, three-wire, AC receptacle that has been wired in accordance with NEC specifications.

4. Turn the power selector switch to the "ON" position and set incubator temperature to 37 degrees C.

Performance Check:

The following Performance Check was used to validate the function of the ALSS in each of the test conditions. Measurements taken during initial operation at standard ambient conditions were used as a baseline for later comparison. The performance check for the ALSS is defined below and will be referenced throughout the Test Condition section.

Procedure:

1. Set up the equipment as described in "test set-up".

2. Record ambient temperature and barometric pressure.

3. Record temperature inside the incubator and examine for fluctuations throughout the duration of the test.

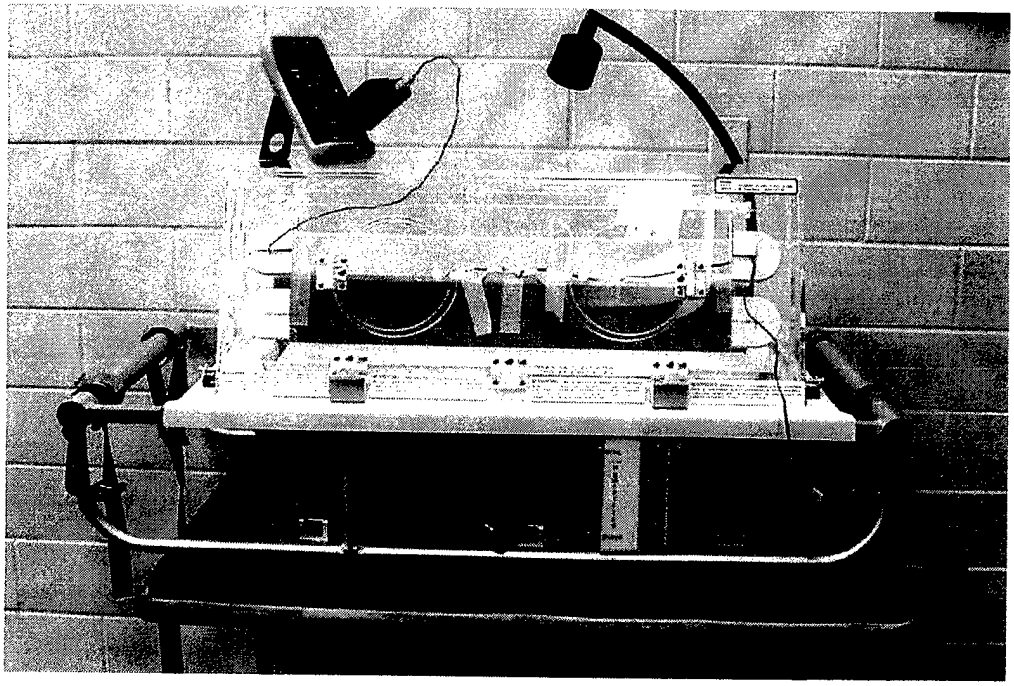

Figure 2. Test Setup

PERFORMANCE CHECK

The above individual performance checks were used to validate the function of the ALSS in each of the test conditions. Measurements taken during initial operation at standard ambient conditions served as a baseline for later comparison. The performance check for the ALSS is as defined above and will be referenced throughout the Test Condition section. Battery operation performance was assessed against manufacturer claims as outlined in the International Biomedical, Inc., Operator's & Service Manual (9).

VIBRATION

Vibration testing is critical to determine, "the resistance of equipment to vibrational stresses expected in its shipment and application environments" (6).

ELECTROMAGNETIC COMPATIBILITY

Electromagnetic compatibility is a primary concern for equipment to be used safely on USAF aeromedical evacuation aircraft. Emissions from medical equipment may cause electromagnetic interference (EMI) with potential influence on aircraft navigation and communications equipment. Medical devices may be susceptible to fields generated by aircraft equipment and malfunction in their presence.

The EUT was evaluated for compliance with MIL-STD 461D & MIL-STD 462D (7 & 8). ASC/ENAI engineers at Wright-Patterson AFB evaluated the electromagnetic compatibility data and determined the airworthiness of the medical device. Specific tests conducted were as follows:

a. Radiated Emissions (RE-102), "Radiated Emissions, Electric Field, 10 kHz to18 GHz.": For Air Force aircraft applications, radiated emissions were measured in a narrow range of frequencies from 2 MHz - 1 GHz. This test measured the amount of EMI emitted by the EUT during operation. It verifies the EUT's potential to affect other equipment susceptible to electromagnetic emissions (i.e., aircraft navigation and communications equipment).

b. Conducted Emissions (CE-102), "Conducted Emissions, Power Leads, 10 kHz to 10 MHz.": For Air Force aircraft applications, conducted emissions were measured throughout the entire band of 10 kHz - 10 MHz. This test measured emissions generated by the EUT along its power supply lines. It was performed to assess the EUT's potential to affect other items connected to the same power source, particularly aircraft systems.

c. Radiated Susceptibility (RS-103), "Radiated Susceptibility, Electric Field, 10 kHz to 40 GHz.": For Air Force aircraft applications, radiated susceptibility was tested in a narrow frequency range from 30 MHz - 12.4 GHz at the following field strength levels: 20 V/M^2 below 1 GHz and 60 V/M^2 above 1 GHz (MIL-STD-461D field strength values from Table IV,

Category Aircraft Internal). This test evaluated the EUT's resistance to predefined levels of EMI generated by antennas both internal and external to the aircraft.

d. Conducted Susceptibility (CS-101), "Conducted Susceptibility, Power Leads, 30 Hz to 50 kHz.": For Air Force aeromedical aircraft applications, conducted susceptibility was tested throughout the entire frequency band, from 30 Hz to 50 kHz. This test evaluated the EUT's ability to "withstand ripple voltages associated with allowable distortion of power source voltage wave forms."

e. Conducted Susceptibility (CS-114), "Conducted Susceptibility, Bulk Cable Injection, 10 kHz to 400 MHz.": For Air Force aeromedical aircraft applications conducted susceptibility was tested throughout the frequency band from 10 kHz to 200 MHz. This test determined whether "simulated currents that will be developed on platform cabling from electromagnetic fields generated by antenna transmission would affect the equipment under test."

f. Conducted Susceptibility (CS-115), "Conducted Susceptibility, Bulk Cable Injection, Impulse Excitation": This test was performed to ensure the EUT could withstand the "fast rise and fall time that may be present due to platform switching operations and external transient environments such as lightning and electromagnetic pulse."

g. Conducted Susceptibility (CS-116), "Conducted Susceptibility, Damped Sinusoidal Transients, Cables and Power Leads, 10 kHz - 100 MHz," respectively. The "basic concept of this test is to simulate electrical current and voltage waveforms occurring in platforms from excitation of natural resonances."

During emissions testing, all the EUT's electrical components/devices were operational for the duration of the test to create a worst case emissions scenario. For both emissions and susceptibility testing, the EUT was tested for operation using 115 VAC/60 Hz and 400 Hz and internal battery power.

THERMAL/HUMIDITY ENVIRONMENTAL CONDITIONS

Extreme temperature and humidity testing determines if aeromedical equipment can be stored and operated during severe environmental conditions without experiencing physical damage or deterioration in performance (6). Extreme environmental conditions can have incapacitating effects on medical equipment including the following: changes in material characteristics and material dimensions, overheating, changes in lubricant viscosity, corrosion, changes in electronic components, and electronic or mechanical failures due to rapid water or frost formation.

HYPOBARIC CONDITIONS

Cabin Pressure/Altitude: Altitude testing is critical for aeromedical evacuation equipment due to potential effects of barometric pressure changes on operation of the equipment. Majority of aircraft, characterized as opportune aircraft, available for use in aeromedical evacuation maintain cabin pressures equivalent to 8,000 - 15,000 ft above sea level. Altitude testing consisted of operating the EUT while ascending from ground level to 15,000 ft, stopping at 2,000 ft increments for performance checks. The rates of ascent and descent were 5,000 ft/min. Testing was conducted in a calibrated man-rated altitude chamber belonging to the Air Force Research Laboratory, Research Chamber Operations.

Rapid Decompression Testing: A rapid decompression (RD) is the loss of aircraft cabin pressurization and subsequent pressure equalization with ambient atmospheric pressure. It is important to assess medical equipment functioning during and after RD so as not to endanger patients, personnel, or the aircraft.

AIRBORNE PERFORMANCE

Airborne performance evaluations are a cost-effective and invaluable means of validating clinical and operational suitability of medical equipment items under actual operating conditions. In-flight test and analysis demonstrates the EUT's ability to provide patient care on board USAF aircraft. Safe and reliable operation is the primary goal of the in-flight evaluation and forms the basis for subsequent recommendations to the users.

Flight qualified AFMEDL aeromedical crewmembers flying on C-9 and C-130 aeromedical evacuation missions conducted this phase of testing. The EUT was positioned and secured to a NATO litter using two NATO litter straps and securing straps supplied by the manufacturer. Then human factor characteristics were evaluated, e.g., securing methods, setup/tear down times and securing locations. Feedback from other aeromedical evacuation crewmembers was obtained concerning EUT human factor considerations.

EXPLOSIVE ATMOSPHERE

The purpose of this test is to demonstrate that operation of the EUT will not ignite a fuel vapor-laden atmosphere.

EVALUATION RESULTS

INITIAL INSPECTION

Initial inspection revealed no manufacturing defects. The unit performed to the

manufacturer's specification. Electrical safety test results showed all parameters to be within referenced guideline limits. Battery endurance testing revealed operation time well within manufacturer's specifications. The battery operated the ALSS heater and air circulation systems for three hours and forty minutes.

VIBRATION

Testing was accomplished through a comparative analysis using the International Biomedical Inc., Neonatal Transport System, Model 20M. See technical report # AFRL-HE-BR-TR-2000-0029 for vibration evaluation results.

ELECTROMAGNETIC COMPATIBILITY

ASC/ENAE, Wright-Patterson AFB certified the EUT for use in the aeromedical evacuation system on all U.S. Air Force aircraft (including small and large body, fixed and rotary wing) while operating from 115VAC/60, 400 Hz and internal battery power. Numerous changes to the ALSS were required and implemented by the manufacturer to achieve successful electromagnetic compatibility. These modifications are discussed in a technical report EMI #B00-3 issued by AFRL/SNZW (11). Note: Recommend the ten-foot skin temperature probe be shortened to 40 inches in length. For proper shielding against electromagnetic interference, a copper-grounding strip attached to the securing plate for the control panel is necessary to provide contact with the Airflow Tray.

THERMAL/HUMIDITY ENVIRONMENTAL CONDITIONS

Testing was accomplished through a comparative analysis using the International Biomedical Inc., Neonatal Transport System, Model 20M. See technical report # AFRL-HE-BR-TR-2000-0029 for thermal/humidity evaluation results.

HYPOBARIC CONDITIONS

1. Cabin Pressure/Altitude: The EUT performed in accordance with manufacturer's specifications throughout testing. The unit was able to maintain infant chamber temperature without system failure up to 15,000 ft cabin altitude.

2. Rapid Decompression: Testing was accomplished through a comparative analysis using the International Biomedical Inc., Neonatal Transport System, Model 20M. See technical report # AFRL-HE-BR-TR-2000-0029 for rapid decompression evaluation results.

AIRBORNE PERFORMANCE

The in-flight evaluation of the EUT was performed on two separate aeromedical evacuation missions (C-9 and C-130). Analysis of performance data indicated this unit was easy to enplane and deplane using two or more crewmembers. The EUT can be plugged directly into Avionics Instruments, Inc., frequency converter or power outlets on the C-9. In certain aircraft such as the C-130/C-141, special training considerations may apply due to aircraft ambient noise affecting audio alarms. The EUT should be positioned to allow visual alarm monitoring throughout all phases of flight. The EUT was positioned on a NATO litter and secured using two NATO litter straps and four additional securing straps provided by the manufacturer.

EXPLOSIVE ATMOSPHERE

The EUT was not evaluated for compliance with MIL-STD-810E (6). WRACC/TIECD engineers at Robins AFB, GA have not evaluated the EUT for explosive atmosphere testing. HQ AMC/SGXPL will coordinate future evaluation of this device for use onboard USAF tanker aircraft.

SUMMARY

AFMEDL engineers found the ALSS conditionally approved for use during all phases of flight on all USAF aircraft (including small and large body, fixed and rotary wing). The ALSS may be used in flight operating on internal battery or powered from 115VAC/60 Hz and 400 Hz aircraft power. The ALSS underwent internal and external Electromagnetic Interference/ Compatibility (EMI) modifications. See below for list of modifications. The ALSS could not meet AFMEDL's established requirements for clinical operation following challenges to hot and cold operational testing (120° F for 2 hours and 32° F for 2 hours). However, the ALSS did operate according to manufacturer's specifications for ambient environments between 59° F to 98.6° F. Aircrews need to be aware of these ambient operating temperature thresholds and operate the ALSS according to manufacturer's guidelines.

The following comments and recommendations apply to this ALSS while in the aeromedical evacuation environment:

a. In certain aircraft such as the C-130/C-141, special training considerations may apply. Consider limitations due to aircraft ambient noise degrading effectiveness of audio alarms. ALSS should be positioned to allow continuous visual alarm monitoring by aeromedical crewmembers throughout all phases of flight.

b. On C-9A aeromedical aircraft, the audible cues could be clearly heard and understood within 7 feet of the ALSS without the use of hearing protection.

c. In keeping with Mil-Std-1472E, all warning, caution and note labels must be written using capital letters. All labels must be positioned to be visible to direct observation and correctly positioned for reading.

d. No transport case/cover was evaluated. Care needs to be taken during transport to prevent ALSS damage and protect it from the environment.

e. Securing the ALSS to the NATO litter requires two standard NATO litter straps and the four securing straps provided by the manufacturer.

f. During infant transport, an occupied ALSS secured to a NATO litter, requires a minimum of four personnel to load and unload the unit into and from the ambulance, as well as enplaning and deplaning from the aircraft. NOTE: AFMEDL SUGGESTS USING THE LITTER RAMP FOR ENPLANING AND DEPLANING ON C-9A AIRCRAFT AND USING THE CARGO RAMP ON C-17, C-130 AND C-141 AIRCRAFT.

g. Frequent opening of the side door may result in ALSS infant chamber over-heating without alarm activation.

h. The oxygen tanks must be mounted in the ALSS to prevent regulators and valves from protruding from the ALSS.

i. The mattress in the infant chamber is not vented to relieve excess pressure during a decompression of the aircraft cabin. Suggest the manufacturer place a ¼" diameter vent hole on mattress ventral surface one inch from mattress edges and in the middle. Also suggest using ¼" velcro strip at cover closure instead of currently used wider velcro strip.

j. Below is a list of EMI modifications that must be implemented prior to use in flight:

1. EMI filter input power lines.
2. EMI filter the power line to the ALSS light at the point where wiring enters the electronics compartment.
3. Place ferrite beads near the circuit card/board to EMI filter signals from the Temperature Probe.
4. EMI shield temperature sensor wire bundle from connector on the control board to temperature sensor ports on Airflow Tray.
5. Ensure the Control panel/display is electrically bonded to the ALSS housing.
6. Incorporate a metalized coating to the underside of the Airflow Tray.
7. Use only 40 inch-long skin temperature probe.
8. A copper-grounding strip needs to be attached to the securing plate for the control panel to provide contact with the Airflow Tray.

k. To answer a question regarding noise attenuation in the infant chamber, AFMEDL conducted a noise level assessment of the NTS infant chamber during vibration testing. The purpose of the test was to examine whether additional noise inside the infant chamber was generated due to a change in manufacturing design of the plexi-glass hood. The evaluated hood

is identical to the ALSS hood and is composed of two separate pieces versus the previous single piece design. The results demonstrated that the new plexi-glass hood does not generate additional environmental noise. Testing showed decreased environmental noise inside the infant chamber when compared to ambient conditions.

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REFERENCES

1. National Fire Protection Agency (NFPA) 99, Health Care Facilities Code
2. Emergency Care Research Institute (ECRI)
3. AFI 41-203, Electrical Shock Hazards
4. AFI 41-201, Equipment Management in Hospitals
5. MIL-STD 1472E, Human Engineering Design Criteria for Military Systems, Equipment, and Facilities.
6. MIL-STD 810E, Environmental Test Methods and Engineering Guidelines.
7. MIL-STD 461D, Electromagnetic Emission and Susceptibility Requirements for the Control of Electromagnetic Interference.
8. MIL-STD-462 D, Measurement of EMI Characteristics.
9. International Biomedical, Inc., Model 185M, Infant Transport Incubator System, Operator's & Service Manual.
10. AFMEDL Procedures Guide, Internal Operating Instruction, Systems Research Branch, Air Force Research Laboratory.
11. AFRL/SNZW Technical Report EMI #B00-3

APPENDIX
MANUFACTURER'S SPECIFICATIONS OF INTERNATIONAL BIOMEDICAL, INC., MODEL 185M, AIRBORN LIFE SUPPORT SYSTEM

SPECIFICATIONS

General

Size:	40.0 in. W. X 19 5/8 in. H. X 22 ½ D.
Weight:	86.9 lbs.
Power Requirements:	115 VAC/60 and 400 Hz and internal rechargeable battery.
Current Draw:	3 amps
Operating time:	Internal batteries: 3 hours of operation @ 37°C ambient temperature. Recharge time 10 hrs on AC, unit off
Environmental	Operating Temperature: (-15°C to 40°C). Humidity: 10 – 95% non-condensing. Pressure: 50 – 106 KPa